

**REMARKS**

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1 and 20 are pending in this application. Claim 1 is amended and claims 4, 5, 7 and 17-19 have been cancelled. No claims have been added. Claims 1 and 20 are the independent claims.

**Specification Objection**

The Examiner states that the amended specification filed on March 8, 2007, is not accepted because the use of trademarks is noted in the amendment, e.g., QuickChange<sup>TM</sup>. The specification has been amended to correct the spelling of the trademark QuikChange<sup>TM</sup>.

MPEP § 608.01(v) states “trademarks should be identified by capitalizing each letter of the mark (in the case of word or letter marks) or otherwise indicating the description of the mark (in the case of marks in the form of a symbol or device or other nontextual form)”. Therefore, Applicants respectfully submit that the amendments to the specification, both filed in the present amendment and the March 8, 2007 Amendment, should be entered because the use of the trademarked term QuikChange<sup>TM</sup> is appropriate.

**Rejections under 35 U.S.C. § 112**

Claims 1, 19 and 20 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 19 has been cancelled and so the rejection of claim 19 is now moot.

Independent claim 1 is directed to a pharmaceutical compound including a particle-forming

protein capable of recognizing a hepatocyte, and a disease-treating target-cell-substance, which is an interferon for treating viral hepatitis. Independent claim 20 is directed to a pharmaceutical compound including a particle-forming protein capable of recognizing a hepatocyte, and a disease-treating target-cell-substance, which is a hepatocyte growth factor for treating hepatic cirrhosis. The Examiner states that in order to provide proof of utility with regard to drugs and their uses, either clinical, *in vivo* or *in vitro* data can be used and must be such to convince one of ordinary skill in the art that the proposed utility is sufficient established. In the attached Rule 1.132 Declaration by experimenter Shunichi Kuroda, experimental data is provided for the physiological activity of a drug in which IFN or HGF is fused to HBsAg protein, which clearly establishes the utility of the pharmaceutical compounds of claims 1 and 20.

Accordingly, Applicants submit that the specification is enabling and respectfully request that the rejection of Claims 1, 19 and 20 under 35 U.S.C. § 112, first paragraph, be withdrawn.

### **Double Patenting Rejections**

Claim 1 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 28 and 30-33 of co-pending application 10/220,125, Claims 1-7 and 9 of co-pending application 10/529,749, and Claims 1 and 2 of co-pending application 10/509,248.

Application No. 10/220,125 relates to hollow nano particles formed of proteins capable of recognizing a living organism and containing living organism cognitive molecules. Application No. 10/529,749 relates to hollow nano particles formed of first proteins, which are particle-forming proteins having living organism cognitive molecules (proteins capable of recognizing a living organism), wherein at least one of the first proteins interacts with a second protein forming a capsid structure. Application No. 10/509,248 relates to hollow nano particles

presenting molecules to be coupled with a specific cell surface molecule such as a growth factor, formed from particle-forming proteins, wherein each hollow nano particles encapsulating a disease-treating target cell substance. All of the above applications also disclose HBsAg as a protein capable of recognizing a living organism.

However, in example embodiments, the target-cell substance (living organism cognitive molecule) is not limited to an interferon or a hepatocyte growth factor. The target-cell substance of example embodiments (e.g., an interferon or a hepatocyte growth factor) serves to effectively introduce a drug into the target organ, e.g., liver. As shown in the experimental data, the treatment effect for viral hepatitis or hepatic cirrhosis may be ensured with a smaller administration amount than that in the sole administration of interferon or hepatocyte growth factor. This effect cannot be obtained by Application Nos. 10/220,125, 10/529,749, and 10/509,248 or the combination of these applications. Therefore, withdrawal of the nonstatutory obviousness-type double patenting rejection is respectfully requested.

**CONCLUSION**

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

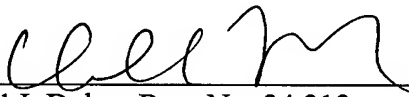
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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By

  
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